

REMARKS

In response to the Office Action mailed July 16, 2003, (hereinafter referred to as "the Office Action") Applicant respectfully requests the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following remarks. The original submitted Claims 1-52 were previously canceled after being correctly renumbered Claims 1-51 in the Office Action mailed March 10, 2003. The renumbering of the originally submitted claims was required because there was no Claim 48 originally submitted. Claims 56-64, 70, 72, 82-84, and 88-90 have been "withdrawn" and the amended numbering in the foregoing claim amendments correctly shows the renumbering of the claims and the renumbering of any dependencies they have on other renumbered claims. Thus, although they are shown as "(Withdrawn)" in AMENDMENTS TO THE CLAIMS, claims 56-64, 70, 72, 82-84, and 88-90 also have been amended by this paper, as shown by the markups.

The Office Action includes indications under "2a" for both the "FINAL" and "non-final" boxes. A Telephonic Interview with the Examiner on October 16, 2003, confirmed the "non-final" indication is correct for the Office Action.

Claims 66, 86 and 87 are canceled. Claims 52-65, 67-85, and 87-90 are pending in the above-captioned application. Claims 56-64, 70, 72, 82-84, and 88-90 are withdrawn from consideration because they are based on non-elected species. Claims 52-55, 65, 67-69, 71, 73-81, and 85 are amended. Claims 52-55, 65, 67-69, 71, 73-81, and 85 are respectfully submitted for further consideration in light of the foregoing claim amendments and the following remarks.

Discussion of Rejections of Claims 52-55, 65, 67-69, 71, 73-81 and 85 under § 103(a)

In the Office Action the Examiner rejected Claims 52-55, 65, 67-69, 71, 73-81 and 85 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,143,248 issued to Kellogg et al. (hereinafter "Kellogg") in view of U.S. Patent No. 5,251,193 issued to Nelson et al. (hereinafter "Nelson"). Applicant respectfully traverses this ground of rejection.

The Office Action rejected Claims 52-55, 65, 67-69, 71, 73-81 and 85, asserting it would have been

"obvious to someone of ordinary skill in the art at the time of the instant invention to practice the biological analyses on compact disk devices with a laser and programming thereon as instantly claimed because Kellogg et al. describes such an assay device which is read by a light source that is well known for such devices to be a laser with a laser reader as also documented by Nelson et al."

In accordance with the MPEP section 2143.03, all the claim limitations must be taught or suggested by the prior art to establish *prima facie* obviousness of a claimed invention. After a careful review of the referenced art, Applicant respectfully submits that the applied references would not have enabled someone of ordinary skill in the art to practice the assay device as claimed herein because neither Kellogg or Nelson, singly or in combination, describe, teach or suggest all the limitations of the claims submitted herein.

Claim 52

Kellogg and Nelson fail to describe, teach or suggest an assay device that includes a "laser readable disk" and "...assay sectors including *analyte binding signal elements within said disk to be scanned by the incident beam*, of and read by, a laser disk reader, wherein the signal elements provide an indication of the presence of an analyte by reflection of the incident beam" (amendments to Claim 52 shown underlined). Nelson discloses an optical disk reader but contains no disclosure relevant for teaching the above-cited limitation. For example, the text of Nelson cited in the Office Action states

"the objective and features of the present invention can be realized not just in "data processing systems" or "computers" in the narrow sense, but may be realized in any technology employing compact optical disks as a medium for storing information, for example compact disc technology." Nelson, Col. 3, lines 1-7.

Although Nelson's disclosure relates generally to optical disk technology, it does not describe the above-cited limitation, and is much too vague to teach or suggest, in whole or in any significant part, the above-cited limitation of amended Claim 52.

Kellogg teaches controlling fluid flow in microplatforms (i.e., disks) using capillary valving mechanisms. Kellogg, Abstract; Col. 14, lines 40-50. However, nowhere does Kellogg even suggest the above-cited limitation. In the section cited in the Office Action, Kellogg merely discloses disks with "windows for external detectors" (Kellogg, Col. 32, lines 11-41) and then later only describes their use with a spectrophotometric light source and detector that measures the *absorbance or transmittance* of light *emitting from the sidewall* of a solution-filled chamber. Kellogg, Col. 35, lines 16-46. This is completely different from a device where "the signal elements provide an indication of the presence of an analyte by *reflection* of the incident beam" of a laser disk reader, as claimed in amended Claim 52.

Additionally, unlike the instantly claimed device, Kellogg fails to disclose, teach or suggest "computer software encoded in said disk which is encoded in an area of said disk which is spatially separate from said assay sectors" instead only making general disclosures related to encoding data, e.g., "optical pits provide means for encoding instrument control programming, user interface information, graphics and sound." Kellogg, col. 32, 7-10. Nelson refers to "information" and "data tracks" on an optical disk (e.g., Nelson col. 1, 14-15; Fig. 1, 24) but also fails to disclose, teach or suggest encoding software "in an area of said disk which is spatially separate from said assay sectors" as claimed in Claim 52, or another such designated area on a disk. Nelson discloses a disk reader capable of reading data placed over the entire disk, stating "since the data tracks on the optical disk 22 are found at distances from R_{\min} to R_{\max} from the center of the disk 40, the optical disk reader 20 must possess the capability of accessing all the data tracks," where Figure 1 indicates R_{\min} defines a inner portion of the disk capable of storing data and R_{\max} defines a outer portion of the disk, which is shown at the outer edge of the disk, capable of storing data. Nelson, Figures 1 and 2; col. 5, 30-34. Thus, Nelson teaches away from "computer software encoded ... in an area of said disk which is spatially separate from said assay sectors" or another such sector area, provides no information suggesting that the encoding should be separated from other sectors on the disk, and certainly does not teach or suggest this claimed feature.

For at least the foregoing reasons, Applicant respectfully submits that a *prima facie* showing of obviousness is not established for amended Claim 52. Accordingly, Applicant requests withdrawal of the 35 U.S.C. § 103(a) rejection and submits that amended Claim 52 is in condition for allowance.

Claims 53 – 55

The Office Action rejected Claims 53-55 as unpatentable over Kellogg in view of Nelson. As these claims are dependent either directly or indirectly from the above-discussed independent Claim 52, Applicant respectfully submits that these claims are also in condition for allowance for at least the same reasons.

Additionally, Claims 53-55 appear to contain further limitations that are not described, taught, or suggested by the prior art. For example, Nelson discloses storing data on an optical disk but fails to teach anything specific or particularly relevant to the limitations in Claims 53-55. The "programming" disclosed in Kellogg may suggest "instrument control programming, user interface information, graphics and sound specific to the application and driver configuration," but Kellogg

fails to describe, teach, or suggest programming that includes "assay interpretative algorithms" and "self-diagnostics" even when describing the spectrophotometric measurements. Kellogg Col. 32, lines 7-10; Col. 35, lines 16-46. Specifically, the Examiner fails to identify any teaching or suggestion in Kellogg or Nelson "wherein said [analyte *binding* signal] elements are provided within said sectors within said disk in a predetermined spatially addressable manner" (Claim 53), that the software of the assay device can include "assay interpretative algorithms" and "self-diagnostics" (Claim 54), or that the "software is capable of uploading diagnostic information to remote locations" (Claim 55). Therefore, Applicant submits that Claims 53-55 are also in condition for allowance for at least these additional reasons.

Claims 65 and 79

Claim 65 is amended herein to include "analyte binding signal elements in a spatially addressable pattern located in an annular area of an outer portion of said disk" and "interpretive software encoded in a spiral track located in an annular area of an inner portion of said disk which is spatially distinct from said elements" (amendments shown underlined). Claim 79 is amended herein to include "address information encoded in said disk spatially adjacent to said assay sectors to provide location information as to said assay sectors, and wherein said assay sectors are positioned about said disk in radially extending spaced relation and said address information is encoded in or on said disk between said assay sectors." To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. Applicant respectfully submits that the referenced art does not describe, teach or suggest all the limitations of amended Claims 65 or 79.

In the Office Action the Examiner has not established that Nelson and Kellogg disclose, teach or suggest the limitations claimed in amended Claims 65 or 79. For example, without specifically addressing the claims the Office Action cites Nelson for "usage of a laser light source and laser reader for compact disk reading," thus apparently relying on Kellogg for describing, teaching or suggesting all the remaining limitations of Claims 65 and 79. However, after a careful review of Kellogg, no such disclosures can be found. Without more specificity of where Kellogg and Nelson clearly disclose the claimed limitations, or why the combination of Kellogg and Nelson renders the claims obvious to one of ordinary skill in the art, *prima facie* obviousness is not established. Accordingly, Applicant respectfully submits that neither Kellogg nor Nelson, alone or

in combination, provide any teaching or suggestion of matter that anticipates or would have made obvious the subject matter defined by Claims 65 and 79 as presented herein.

For at least the foregoing reasons, Applicant requests withdrawal of the 35 U.S.C. § 103(a) rejections and respectfully submits that amended Claims 65 and 79 are thereby in condition for allowance.

Claims 67-69, 71, 73-78, 80, and 85

In the Office Action, the Examiner rejected Claims 67-69, 71, 73-78, 80, and 85 as being unpatentable over Kellogg in view of Nelson. As these claims depend directly or indirectly from the above-discussed independent Claims 65 and 79, Applicant respectfully submits that Claims 67-69, 71, 73-78, 80, and 85 are also in condition for allowance for at least the same reasons.

Additionally, Applicant respectfully submits that Claims 67-69, 71, 73-78, 80, and 85 contain limitations which the referenced art fails to describe, teach or suggest, and the Office Action does not cite their disclosure in Kellogg or Nelson. Therefore, a *prima facie* showing of obviousness has not been established for Claims 67-69, 71, 73-78, 80, and 85. Accordingly, Applicant respectfully submits that Claims 67-69, 71, 73-78, 80, and 85 are in condition for allowance at least for this reason.

CONCLUSION

The applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims for patentability purposes pursuant to statutory section 103, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. In light of these amendments and remarks, reconsideration and withdrawal of the outstanding rejections is respectfully requested.

Any claim amendments which are not specifically discussed in the above remarks are not made for patentability purposes, and it is believed that the claims would satisfy the statutory requirements for patentability without the entry of such amendments. Rather, these amendments have only been made to increase claim readability, to improve grammar, and to reduce the time and effort required of those in the art to clearly understand the scope of the claim language.

If the Examiner has any questions which may be answered by telephone, he is invited to call Gregory A. Hermanson, of Knobbe, Martens, Olson & Bear L.L.P., at 619-235-8610.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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By: Gregory A. Hermanson

Gregory A. Hermanson
Registration No. 53,018
Attorney of Record
Customer No. 20,995
(619) 235-8550

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